

REMARKS

Claims 1 to 33 were examined. Claims 1-3, 9, 12-15, 18, 23-28, 30 and 32 have been amended. Claims 4-8, 10, 11, 16, 17, 19-22, 29, 31 and 33 remain unchanged. Claims 1-33 now stand in the application.

Claim 1 has been amended by replacing the phrase "possibly containing" with "containing or suspected of containing". Claim 1 has also been amended by replacing the phrase "one or more" with the phrase "a multitude of". Finally, claim 1 has been amended by inserting the phrase "wherein the multitude of steroid hormones includes at least one hormone selected from the group consisting of estradiol, testosterone and DHEAs".

Support for the phrase "a multitude of" is found in the examples which show that 11 steroids were analyzed. Support for "estradiol, testosterone and DHEAs" is also found in the examples, and Figures 1, 2 and 6. Claims 2-3, 9, 12-15, 18, 23-28, 30 and 32 have been amended in a similar manner.

Claim 12 has been amended by adding the term "comprising a column" to provide an antecedent for "the column".

Claim 32 has been amended by adding the method steps of claim 1. Support for the steps can be found throughout the specification and in claim 1 has originally filed.

Abstract

The Examiner states that the Abstract is objected to because of the inclusion of legal phraseology such as "comprise" and "comprising".

Please delete the section labeled "Abstract of the Disclosure" on page 40 of the specification and replace such deleted section with a replacement section as described below:

Replacement Section:

Abstract of the Disclosure

Methods, systems and kits for the simultaneous or sequential analysis of one or more a multitude of steroid hormones by mass spectrometry are disclosed. The methods require minimal sample size and minimal preparation time. The methods comprise- include ionizing the hormones and analyzing the hormones by mass spectrometry. In addition, methods, systems and kits for the simultaneous or sequential analysis of steroid hormones are disclosed comprising including ionization of the steroid hormones by photoionization.

Claim rejections 35 USC § 112

The Examiner has rejected claims 1 to 31 for being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claims 1, 27, 28, and 30

The Examiner states that the preamble and part (a) of the claim are not commensurate in scope with one another because the preamble recites a sample "possibly containing one or more steroid hormones" and part (a) positively recites that the sample does contain the one or more steroid hormones.

Applicant has amended claims 1 and 28 by replacing the word "possibly" in the preamble with the term "containing or suspected of containing". This term was added to part (a) of claims 1 and 28.

Applicant has amended claim 27 by replacing the word "possibly" in the preamble with the term "contains or is suspected of containing".

Claim 12

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The Examiner states that there is no antecedent for "the column". Applicant has amended claim 12 by adding the term "comprising a column".

Claims 32 to 33

The Examiner states that claims 32 to 33 provide for the use of a mass spectrometer but since the claim does not set forth any steps involved in the method process, it is unclear what method/process applicant is intending to encompass.

Claims 32 and 33 have been amended to include method steps as follows:

- (a) providing a sample containing or suspected of containing a multitude of steroid hormones;
- (b) deproteinating the sample;
- (c) separating the multitude of steroid hormones from the sample; and
- (d) analyzing the multitude of steroid hormones using a mass spectrometer.

Claim rejections 35 USC § 101

The Examiner states that claims 32 to 33 provide for the use of a mass spectrometer but since the claim does not set forth any steps involved in the method process, it is unclear what method/process applicant is intending to encompass.

Claims 32 and 33 have been amended to include method steps as described above.

Claim rejections 35 USC § 102

Kissmeyer et al.

The Examiner objected to claims 1-3, 6, 9-10, 12-16, 18, 21, 24, 26-29 and 32-33 citing Kissmeyer et al. Kissmeyer et al. discloses a method and system for determining vitamin D analogs in human and pig serum using 1.0 ml sample.

Applicants amended the claims by specifying that a multitude of steroid hormones are analyzed. Support for this amendment is found throughout the specification and in particular in the examples. Kissmeyer et al. disclosed the analysis of vitamin D (EB1089) and its derivatives using a laborious method of protein extraction, followed by MF C18 SPE column purification and further LC-MS analysis. Kissmeyer et al. did not disclose the analysis of more than one steroid hormone. Accordingly, Kissmeyer et al. does not anticipate the amended claims.

Jonsson et al.

The Examiner objected to claims 1-3, 8-10, 12, 14-16, 18, 21, 24, 26-29 and 32-33 citing Jonsson et al. Jonsson et al. discloses a method and system for the determination of cortisol in saliva.

Applicants amended the claims by specifying that a multitude of steroid hormones are analyzed. Jonsson et al. disclosed the analysis of one steroid, cortisol, from saliva. Jonsson et al. did not disclose the analysis of more than one steroid hormone. Accordingly, Jonsson et al. does not anticipate the amended claims.

Kao et al.

The Examiner objected to claims 1-4, 6, 9, 12-16, 18, 21, 23, 25, 27-29 and 32-33 citing Kao et al. Kao et al. discloses a method and system for simultaneously analyzing at least three components of the adrenal pathway using LC-tandem mass spectrometry.

Kao et al. discloses a method to assess adrenal dysfunction. The adrenal glands are endocrine glands that sit on top of the kidneys and are chiefly responsible for regulating the stress response through the synthesis of corticosteroids and catecholamines, including cortisol and adrenaline. Kao et al. did not disclose the analysis of estradiol,

testosterone or DHEAs. The Applicant has amended the claims by reciting the analysis of at least one of these steroid hormones. Support for this amendment is found throughout the specification and in particular in Examples 1 and 2. Accordingly, Kao et al. does not anticipate the amended claims. Applicant requests that the rejection be withdrawn.

Fredline et al.

The Examiner objected to claims 1-6, 9, 12, 14-16, 18, 22, 24, 26-29 and 32-33 citing Fredline et al. Fredline et al. discloses a method and system for the determination of aldosterone in samples of plasma or blood.

Applicants amended the claims by specifying that a multitude of steroid hormones are analyzed. Fredline et al. discloses the analysis of one steroid, aldosterone, using HPLC- APCI- MS/MS. Fredline et al. did not disclose the analysis of more than one steroid hormone. Accordingly, Fredline et al. does not anticipate the amended claims.

Leinonen et al.

The Examiner objected to claims 1-3, 7, 9, 12-21, 23, 25, 27-29 and 32-33 citing Leinonen et al. Leinonen et al. discloses a method and system for the determination of anabolic steroids in urine using LC-mass spectrometry.

Leinonen et al. teaches the analysis of three "free" anabolic steroids in urine (oxandrolone, hydroxyl-4-chlorohydro-methyltestosterone, hydroxystanazolol). The urine samples were extracted by a complex process using sodium hydrogencarbonate-potassium carbonate mixture and extracted with diethyl ether. Finally, Leiononen et al. concluded that photoionization was not as effective as ESI, and therefore Leionone et al. teaches away from the present invention.

As stated above, the claims have been amended to recite that at least one of the hormones analyzed is selected from the group consisting of estradiol, testosterone or DHEAs. Leinonen et al. does not disclose the analysis of estradiol, testosterone or

DHEAs. Leinonen et al. discloses the analysis of anabolic steroids. Anabolic steroids, also known as anabolic-androgenic steroids or AAS, are a class of steroid hormones related to the hormone testosterone. They increase protein synthesis within cells, which results in the buildup of cellular tissue (anabolism), especially in muscles. Accordingly, Leinonen et al. does not anticipate the amended claims.

Vogeser et al.

The Examiner objected to claims 1-3, 6, 11-16, 18, 21, 23, 26-29 and 32-33 citing Vogeser et al. Vogeser et al. discloses a method and system for the determination of cortisol in serum.

Vogeser et al. disclose the analysis of one steroid (cortisol) in serum samples precipitated with methanol/zinc sulfate in a three step extraction process. Applicants have amended the claims by specifying that a multitude of steroid hormones are analyzed. Vogeser et al. did not disclose the analysis of more than one steroid hormone. Accordingly, Vogeser et al. does not anticipate the amended claims.

Claim rejections 35 USC § 103(a)

The Examiner objected to claims 30 and 31 on the basis of obviousness citing Kissmeyer et al., Jonsson et al., Kao et al., Fredline et al., Leinonen et al. or Vogeser et al.

The Examiner states that it would have been obvious for the ordinary skilled worker to incorporate all of the needed/required reagents and instrumentation required for analyzing steroid hormones in accordance with any of the methods taught by the cited art.

Applicant amended claim 30 by specifying that the kit is for the analysis of a multitude of steroid hormones and that at least one of the steroid hormones is selected from the group consisting of estradiol, testosterone and DHEAs. As argued above, the cited art does not disclose the analysis of a multitude of steroid hormones wherein at least one

of the steroid hormones is selected from the group consisting of estradiol, testosterone and DHEAs. Accordingly, the cited art does not include each and every element of new claims 30 and 31, and therefore new claims 30 and 31 are not obvious in view of the cited art.

Applicant believes that all of the issues addressed in the outstanding Action have been addressed in this response, and thus request allowance of the application.

In the event that any issues remain, the Examiner is invited to telephone the undersigned at (416) 865-7367 with any proposal to advance prosecution.

Yours very truly,

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Date



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